

Amendment and Response

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Serial No.: 09/965,610

Confirmation No.: 8132

Filed: 26 September 2001

For: COMPOSITION FOR THE TRANSDERMAL DELIVERY OF FENTANYL

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Cent

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fentanyl.

13. (AMENDED) The compositions of claim 10 wherein the concentration of the delivery enhancing adjuvant is from about 5% to about 40% by weight based on the total weight of the composition.

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14. (AMENDED) The composition of claim 34 wherein the skin permeation enhancer is tetraglycol.

15. (AMENDED) The composition of claim 34 wherein the skin permeation enhancer is methyl laurate.

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23. (AMENDED) A pressure sensitive adhesive composition for the transdermal delivery of fentanyl comprising:

(a) an acrylate polymer;

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; and

(c) a delivery enhancing adjuvant selected from the group consisting of methyl laurate, tetraglycol, and mixtures thereof;

wherein the composition is substantially free of undissolved fentanyl.

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25. (AMENDED) The composition of claim 23 wherein the acrylate polymer comprises:

(a) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and

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center

(b) one or more ethylenically unsaturated B monomers copolymerizable with the A monomers.

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30. (AMENDED) A method of providing sustained analgesia to a mammal comprising delivering fentanyl to a mammal via a transdermal drug delivery device in an amount of about 0.5 to about 5.0 mg/day thereby causing the serum concentration of fentanyl in the mammal to be about 0.2 to about 10 ng/mL for a period of time from about 4 to about 14 days, wherein the device includes a composition comprising an acrylate polymer and about 8% to about 30% by weight fentanyl based on the total weight of the composition, wherein the composition is substantially free of undissolved fentanyl.

34. (NEW) The composition of claim 10 wherein the delivery enhancing adjuvant is a skin permeation enhancer.

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35. (NEW) A transdermal drug delivery composition comprising:

(a) a copolymer comprising:

- (i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and
- (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; wherein the B monomers are selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N, N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fentanyl.

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36. (NEW) A transdermal drug delivery composition comprising:

(a) a copolymer comprising:

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only
- (i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and
 - (ii) about 5% to about 45% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; wherein the B monomers are selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N, N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fentanyl.

37. (NEW) A transdermal drug delivery device comprising a composition comprising:

(a) a copolymer comprising:

- (i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and
- (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fentanyl; and

wherein the drug delivery device delivers fentanyl to a mammal in an amount of about 0.5

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to about 5.0 mg/day thereby causing the serum concentration of fentanyl in the mammal to be about 0.2 to about 10 ng/mL for a period of time from about 4 to about 14 days.

38. (NEW) A transdermal drug delivery composition comprising:

(a) a copolymer comprising:

- (i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and
- (ii) about 5% to about 45% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; wherein the B monomers are selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N, N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof;

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; and

(c) a delivery enhancing adjuvant selected from the group consisting of methyl laurate, tetraglycol, and mixtures thereof;

wherein the composition is substantially free of undissolved fentanyl.